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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,825	06/24/2003	David J. Yonce	279.669US1	7977

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,825	<b>Applicant(s)</b> YONCE, DAVID J.	
	<b>Examiner</b> Christopher A. Flory	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/17/03 &amp; 2/14/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "300" has been used to designate both Step 1 (Figure 3) and depolarization detector circuit (Figure 4). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gauglitz (US Patent 5,231,990).

Regarding claims 1,2, 15 and 17, Gauglitz'990 discloses a device (Figure 1, ECG monitor system 10) comprising a first, second and third input terminals (Fig. 2, analog input channels 102) with attached first, second, and third external electrodes (ECG electrode leads 12); a depolarization detector circuit (any of the ASICs 100 as disclosed, or a combination thereof, can be configured to function as a three- to fifteen-lead ECG monitoring system; column 1, line 60 through column 2, line 19; column 3, lines 3-53; column 13, lines 4-14); at least one pace pulse detector circuit capable of detecting at least one of pace pulse amplitude or pulse width (Fig. 2, pacer detect circuit 122; column 16, lines 1-43); and a logic circuit coupled to the pace pulse detector circuit (controller 24; column 3, lines 21-25).

Regarding claims 8 and 19, Gauglitz'990 discloses an ECG monitor system (10) comprising one or a combination of any number of ASICs (100) which can be configured as a depolarization detector circuit, pace pulse detector circuit (122), pacer delay circuit (130), or pacer blanking circuit (132) connected by a controller 24. As disclosed, the Gauglitz'990 device is capable of performing the methods claimed in the instant application including: receiving heart signals from the external electrodes; detecting respective electric fields (polarity) of at least one first and at least one second pacing pulses delivered to the heart (column 15, lines 51-68); detecting at least one of pace pulse amplitude, pulse width, polarity or time difference between the pace pulse and a corresponding heart depolarization (column 16, lines 1-43); and classifying the pace pulses by location in either an atrium or a ventricle based upon the signal polarities or one of the other electrical or physiologic computations herein described. It

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is understood that the clocking device implemented in the pacer delay and blanking circuits would also be capable of being implemented by the controller (24) to measure the time difference between the trailing edge of a pacing pulse as defined by the comparators in the pace detector circuit and the leading edge of a ventricular depolarization (R-wave) as recognized by the ASIC configured as a depolarization detector circuit. Therefore, the instant application does not distinguish over the Gauglitz'990 system.

Regarding claims 3-6, 9-12, and 18, Gauglitz'990 shows the three electrodes being arranged with first electrode near the right arm (RA), second electrode near the left arm (LA), and third electrode below the heart or on the left leg (LL) (Fig. 1); such that vectors I, II and III are defined between the electrodes with first electrode negative with respect to the second and third electrodes, the second electrode positive with respect to the first and negative with respect to the third electrode, and the third electrode positive with respect to the first and second electrodes (column 7, line 35 through column 9, line 2; Tables 1 and 2). This 3-lead arrangement of surface EKG electrodes is well known to those in the art and is commonly referred to as Einthoven's triangle.

Specifically regarding claims 4-6 and 12, the polarity recorded along any of the claimed leads is governed by elementary properties of physics inherent in the physical placement of the external electrodes and the spatial orientation of the implanted bipolar pacing leads being monitored by the system. Thus, given the placement and orientation of the atrial and ventricular pacing leads as they are disclosed in the instant application,

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the polarity of leads I, II, and III in the Gauglitz'990 device would behave identically given identical input criteria, and is therefore considered capable of assigning a pace pulse to either an atrial or a ventricular lead based upon the polarity read across leads II and III (column 15, lines 51-68). Therefore the claims of the instant application do not distinguish over the device disclosed in the Gauglitz'990 patent.

Regarding claims 7, 13, 16, and 20, the system of Gauglitz'990 as disclosed can be configured to consist of a pace pulse detector circuit and pacing blanking circuit (column 13, line 56 through column 14, line 20) working parallel to a depolarization detection circuit connected to the same controller such that the system would be capable of marking a detected pacing pulse, marking a detected depolarization, and determining whether that depolarization has occurred within a predetermined time period of the pace pulse (e.g. within the timeframe of the pacer blanking circuit), and then make use of that information to assign a location classification to the marked pace pulse (column 15, line 23 through column 16, line 42).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauglitz'990 in view of Johnson and Swartz (*A Simplified Approach to Electrocardiography*, 1986, Chapters 3 and 5).

Gauglitz'990 discloses the current invention substantially as claimed except for displaying an indication of the location classification in correspondence with at least one of the first and second pace pulses on the electrocardiogram. In the same field of endeavor, the Johnson and Swartz reference teaches an electrocardiogram displaying the axial location classification of a given electrical signal originating within the heart for the advantages of chart readability and diagnosing electrocardiographic abnormalities based on axial deviations (Johnson and Swartz, *A Simplified Approach to Electrocardiography*, pp. 23-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the indication of a given (pacing) signal's location on the EKG readout of the Gauglitz'990 device for the same advantages of chart readability and diagnosis of functional abnormalities. (motivation to combine provided by Johnson and Swartz, *A Simplified Approach to Electrocardiography*, pp. 23-25).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

caf

  
George Manuel  
Primary Examiner